My 30 Years of Caring for Patients with Symptomatic Vascular Disease

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*Chief Medical Officer Medtronic Peripheral Vascular Health

28th TCTAP

Disclosure Statement of Financial Interest

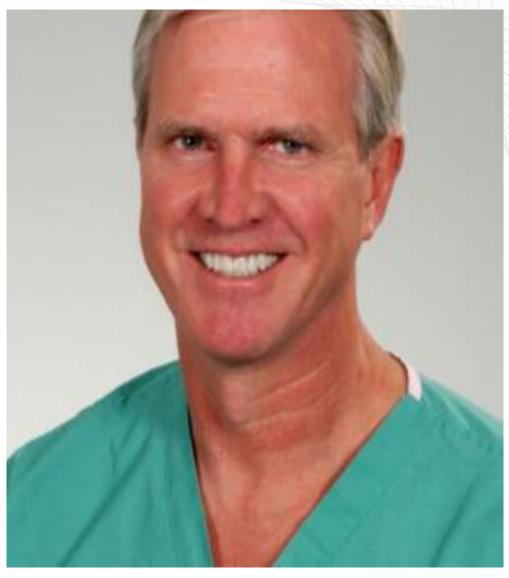
- Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.
- <u>Affiliation/Financial Relationship</u>
 - Employee (Chief Medical Officer)
 - Board Member, Stock Ownership

<u>Company</u>

Medtronic Syntervention



Dr. Christopher White



Dr. Stephen Ramee

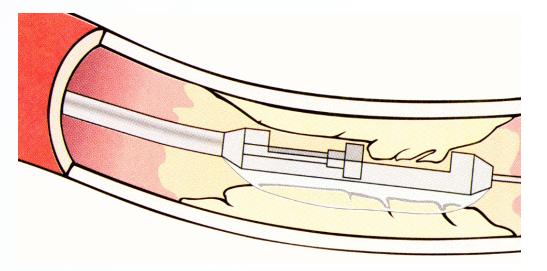


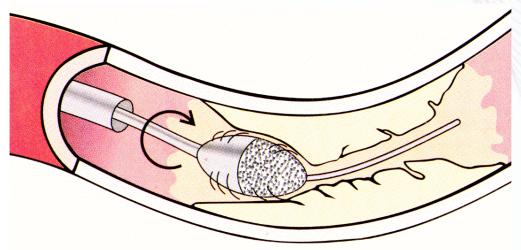


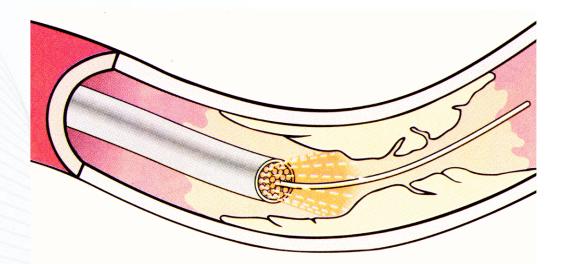
PTCA State of the Art 1987-1990

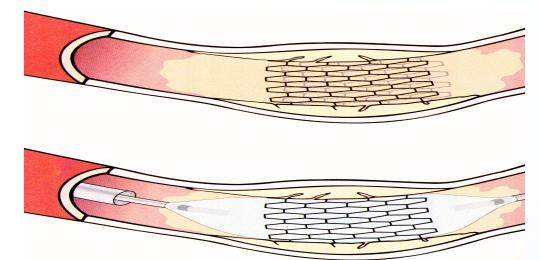
- POBA was king No FDA approved stents
- Technical success: 80-85%
- Acute dissection and elastic recoil common
- Acute vessel closure: 3-8%
 - Chest pain,
 - Acute ST segment elevation MI
 - Hemodynamic instability
- Need for emergency CABG: 2-5%
- Restenosis rates: 30-50%

1990-1995: New Angioplasty Devices



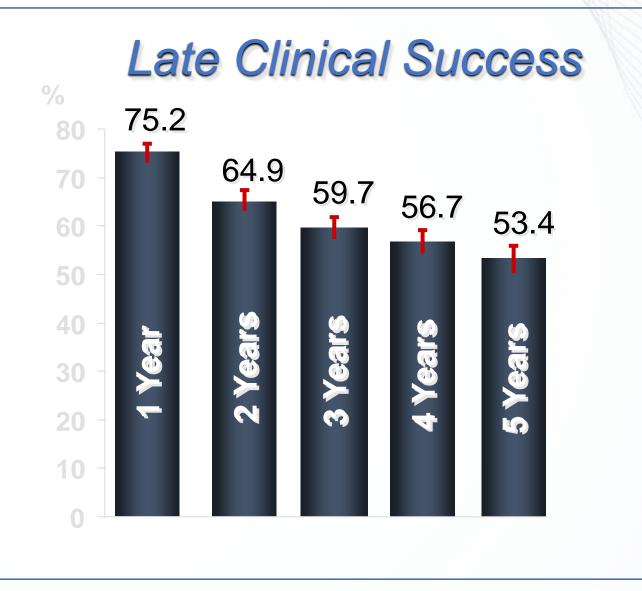






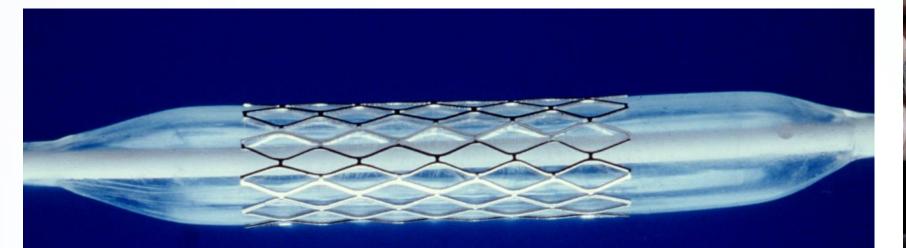
Results of Iliac balloon Angioplasty

- 667 iliac procedures analyzed
- One month clinical success 90.2%

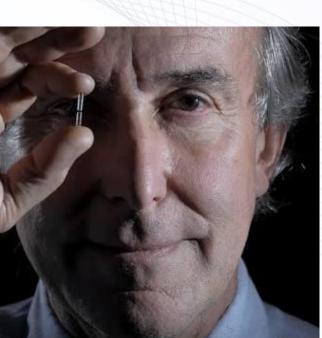


Ann Surg 1987;206:403-13

The Stent Era Begins



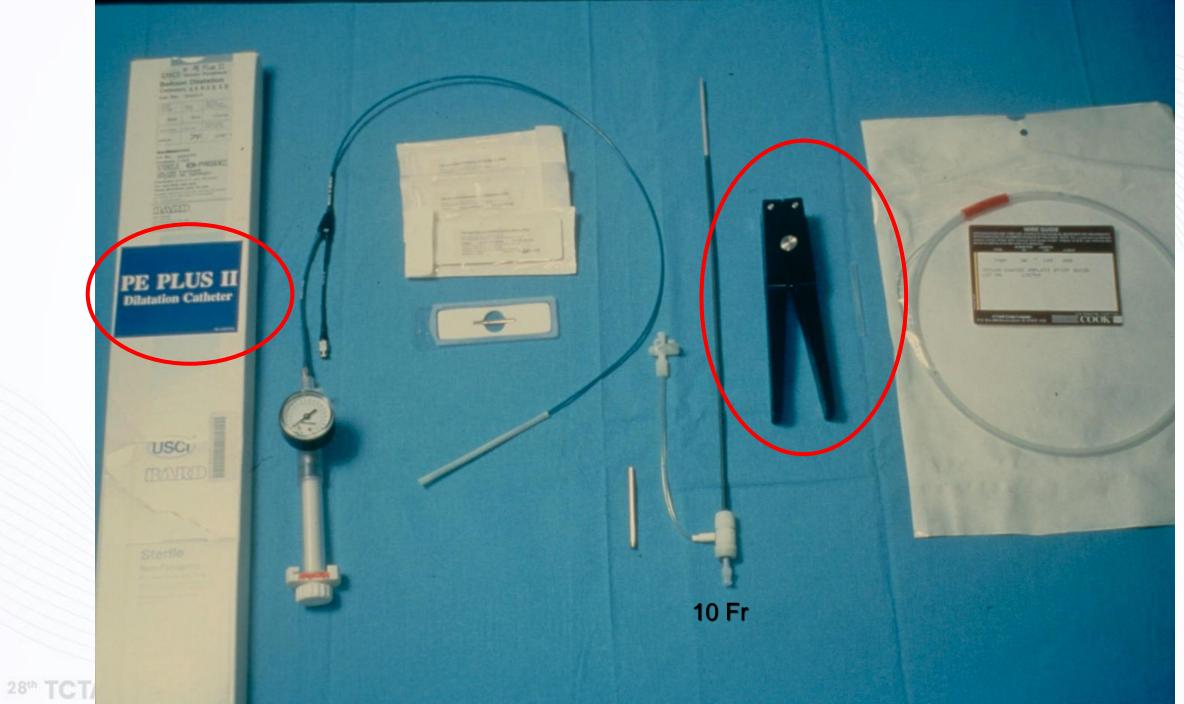
The Palmaz 308 iliac stent

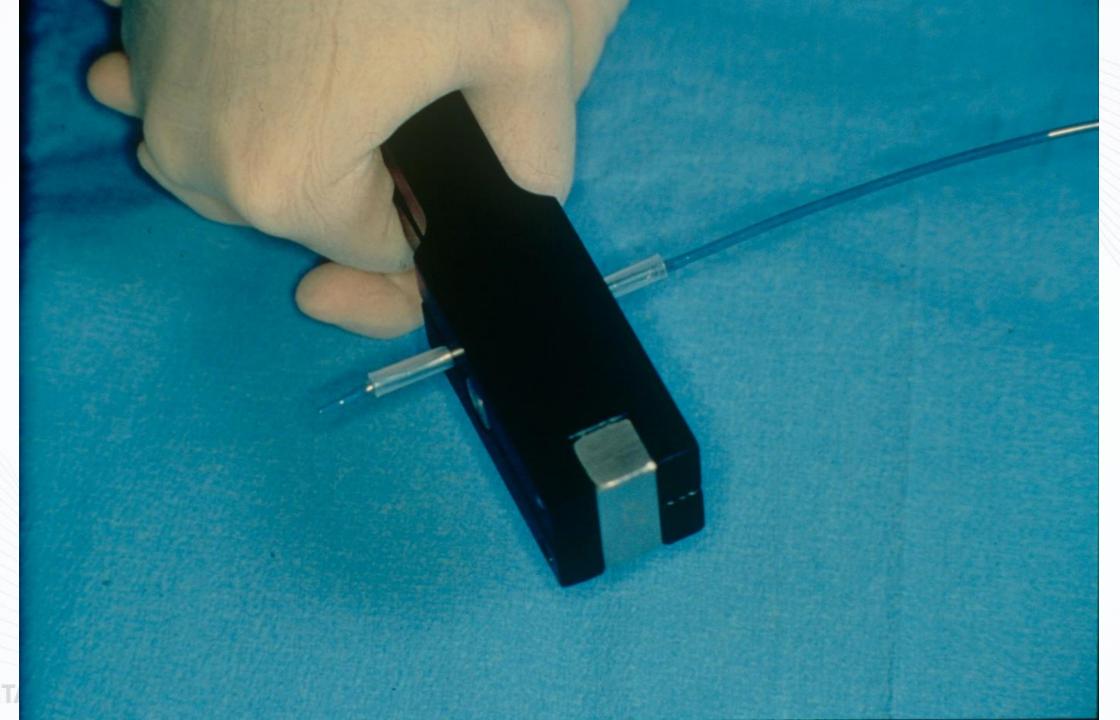


Julio Palmaz, MD

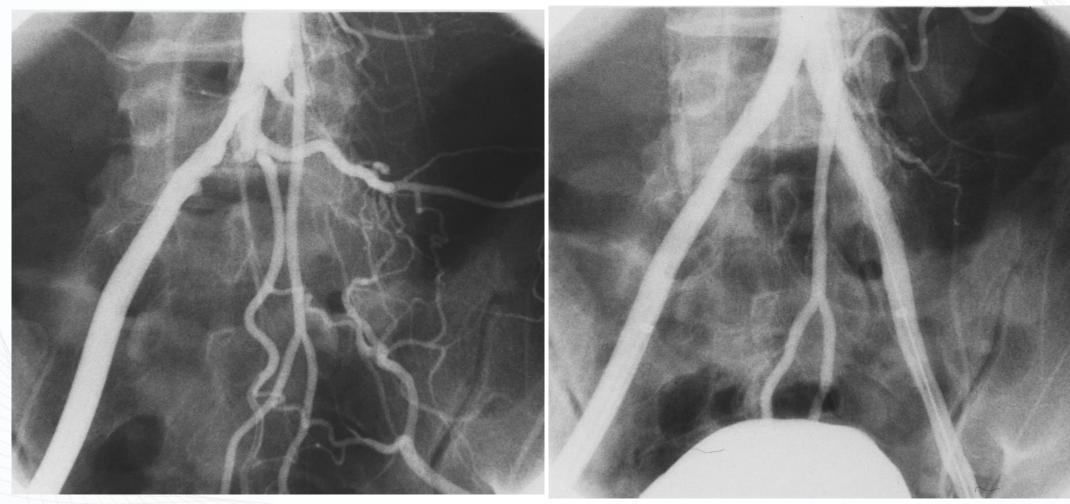








Bilateral Iliac Stenting



PERIPHERAL

15-Year Patency and Life Expectancy After Primary Stenting Guided by Intravascular Ultrasound for Iliac Artery Lesions in Peripheral Arterial Disease



Hisao Kumakura, MD, PHD, Hiroyoshi Kanai, MD, PHD, Yoshihiro Araki, MD, PHD, Yoshiaki Hojo, MD, Toshiya Iwasaki, MD, Shuichi Ichikawa, MD, PHD

ABSTRACT

OBJECTIVES The purpose of this study was to evaluate 15-year patency and life expectancy after endovascular treatment (EVT) with primary stenting guided by intravascular ultrasound (IVUS) for iliac artery lesions.

BACKGROUND Fifteen-year patency, factors causing restenosis, and survival after IVUS-guided EVT are unclear based on the TransAtlantic Inter-Society Consensus II (TASC-II) classification in peripheral arterial disease (PAD).

METHODS EVT was performed for 507 lesions in 455 patients with PAD. The 15-year endpoints were primary, primaryassisted, and secondary patency; overall survival; freedom from major adverse cardiovascular events (MACE); and freedom from major adverse cardiovascular and limb events (MACLE).

RESULTS The 5-, 10-, and 15-year primary and secondary patencies were 89%, 83%, and 75%, respectively, and 92%, 91%, and 91%, respectively. There were no significant differences among TASC-II categories.

CONCLUSIONS IVUS-guided stenting for the iliac artery had favorable 15-year patency in all TASC categories. Life expectancy after EVT was poor, but stenting is feasible for patients with PAD. (J Am Coll Cardiol Intv 2015;8:1893–901) © 2015 by the American College of Cardiology Foundation.

Image Guided Iliac Stenting

- EVT performed for 507 iliac lesions in 455 patients at one Japanese Center
- The 5-, 10-, and 15-year primary and secondary patencies were 89%, 83%, and 75%, respectively, and 92%, 91%, and 91%, respectively
- No significant differences amongst TASC-II categories

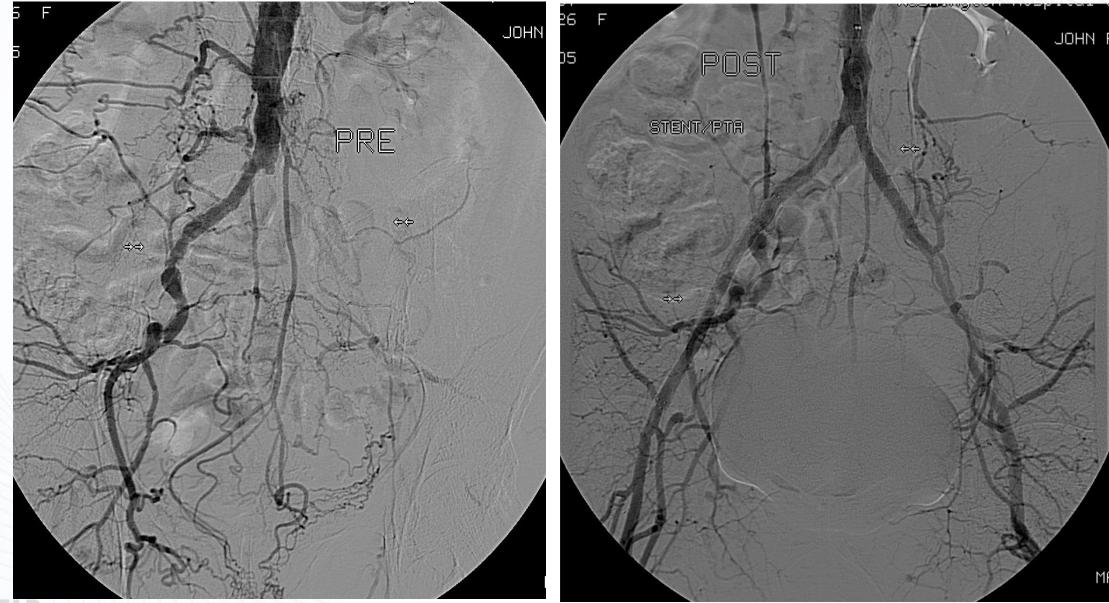
Bilateral iliac occlusions Left Radial approach



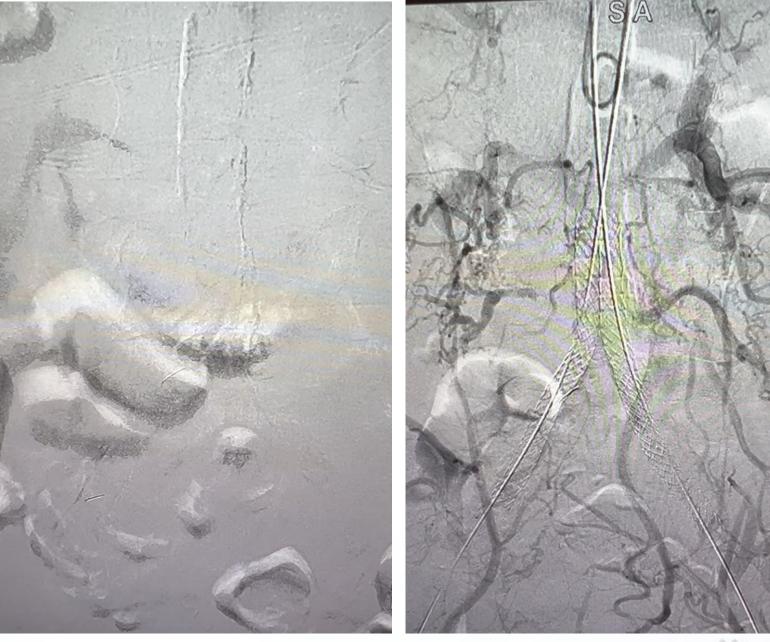


28th TCTA

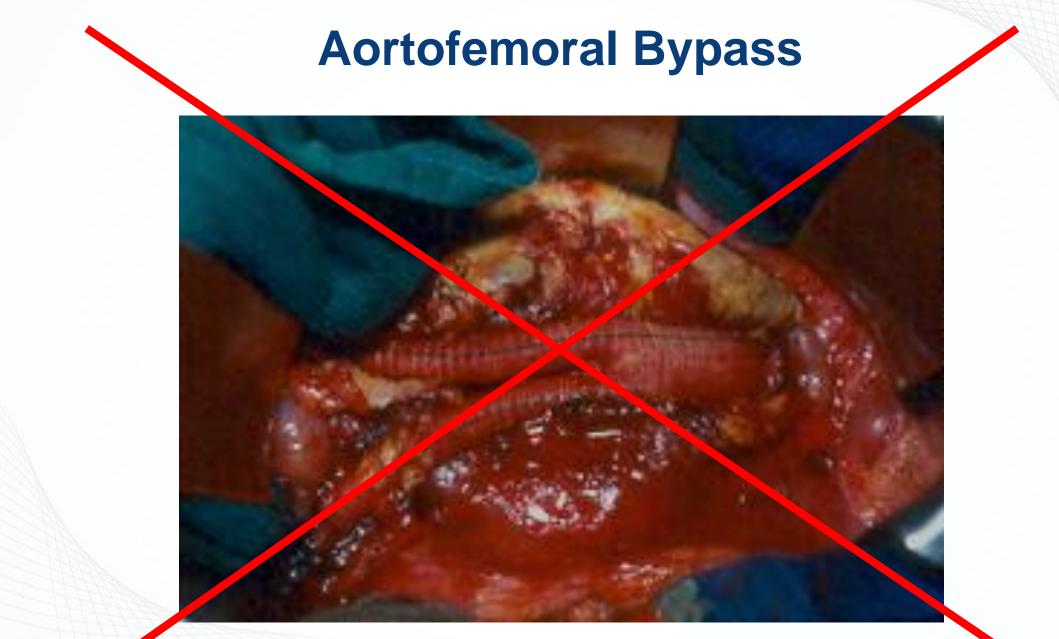
6 Fr Sheath from left radial artery



Aortic Occlusion

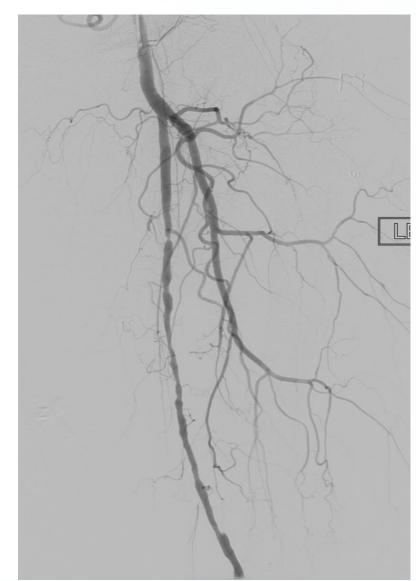


28th TCTAP

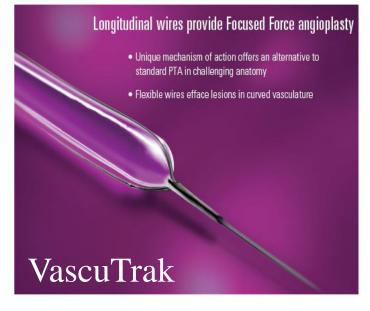


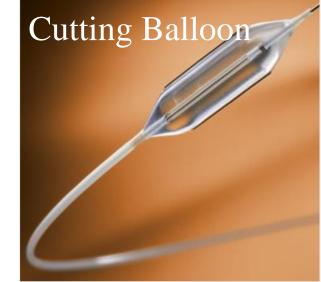
Challenges of the SFA

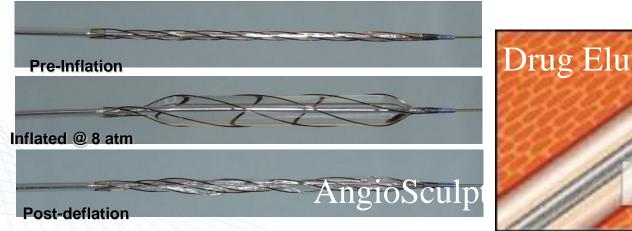
- Diffuse disease
- Long occlusions
- Heavy calcification
- Associated disease of the infrapopliteal run-off vessels
- Complex
 mechanical forces



The Evolution of Balloon Technologies

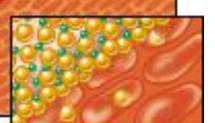




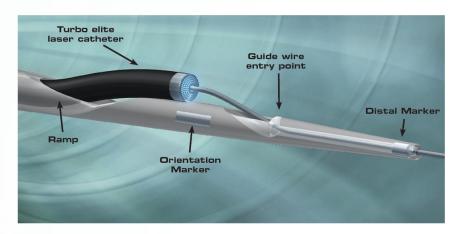


Drug Eluting Balloon

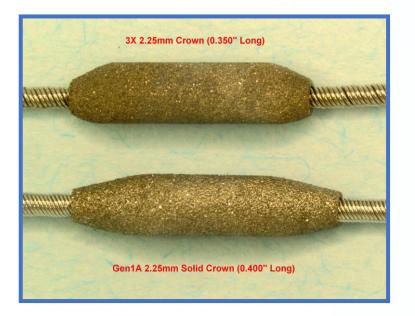




Laser and Atherectomy Devices



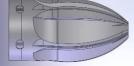










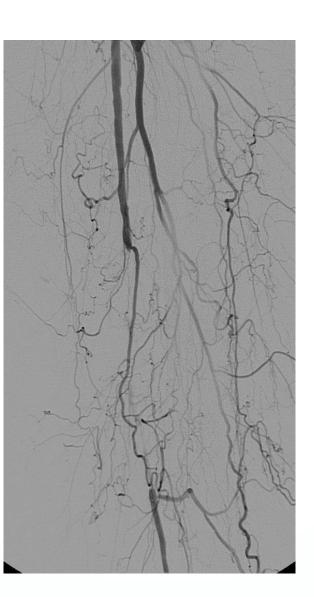


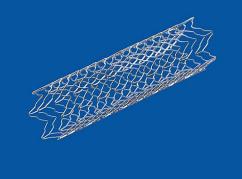


Nitinol Stents for the SFA











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The Drug Eluting Balloon ERA Begins

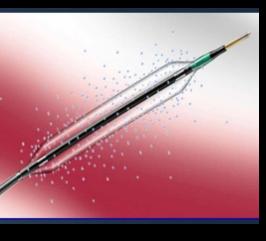
Paclitaxel Balloon Coating, a Novel Method for Prevention and Therapy of Restenosis

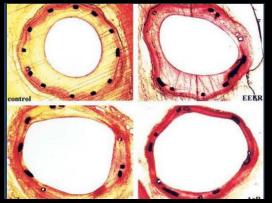
Bruno Scheller, MD; Ulrich Speck, PhD; Claudia Abramjuk, DVM; Ulrich Bernhardt, PhD; Michael Böhm, MD; Georg Nickenig MD

Background—Drug-eluting stents have shown promising antirestenotic effects in clinical trials. Non-stent-based local delivery of antiproliferative drugs may offer additional flexibility and also reach vessel areas beyond the immediate stent coverage. The aim of the present study was to evaluate a novel method of local drug delivery based on angioplasty balloons.
 Methods and Results—Stainless steel stents (n=40; diameter, 3.0 to 3.5 mm; length, 18 mm) were implanted in the left anterior descending and circumflex coronary arteries of domestic pigs. Both conventional uncoated and 3 different types of paclitaxel-coated, percutaneous transluminal coronary angioplasty balloons (contact with vessel wall for 1 minute) were used. No difference in short-term tolerance between coated and uncoated balloons and no signs of thrombotic events were observed. Quantitative angiography and histomorphometry of the stented arteries asserted the statistical equality of the baseline parameters between the control and the 3 treatment groups. Paclitaxel balloon coating led to a marked, dose-dependent reduction of parameters characterizing in-stent restenosis (reduction of neointimal area up to 63%). Despite the marked reduction in neointimal proliferation, endothelialization of stent struts was present in all samples. There was no evidence of a significant inflammatory response in the neighborhood of the stent struts.

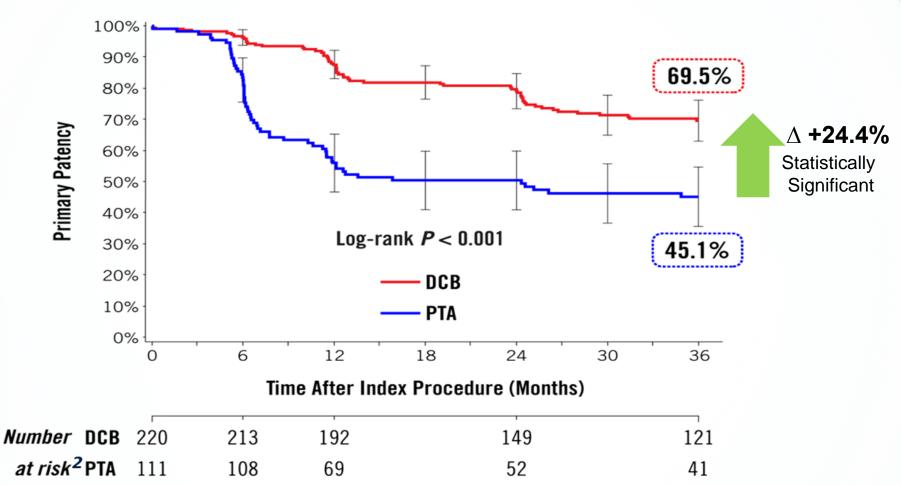
Conclusions—Paclitaxel balloon coating is safe, and it effectively inhibits restenosis after coronary angioplasty with stent implantation in the porcine model. The degree of reduction in neointimal formation was comparable to that achieved with drug-eluting stents. (Circulation. 2004;110:810-814.)

Key Words: restenosis angioplasty angioplasty





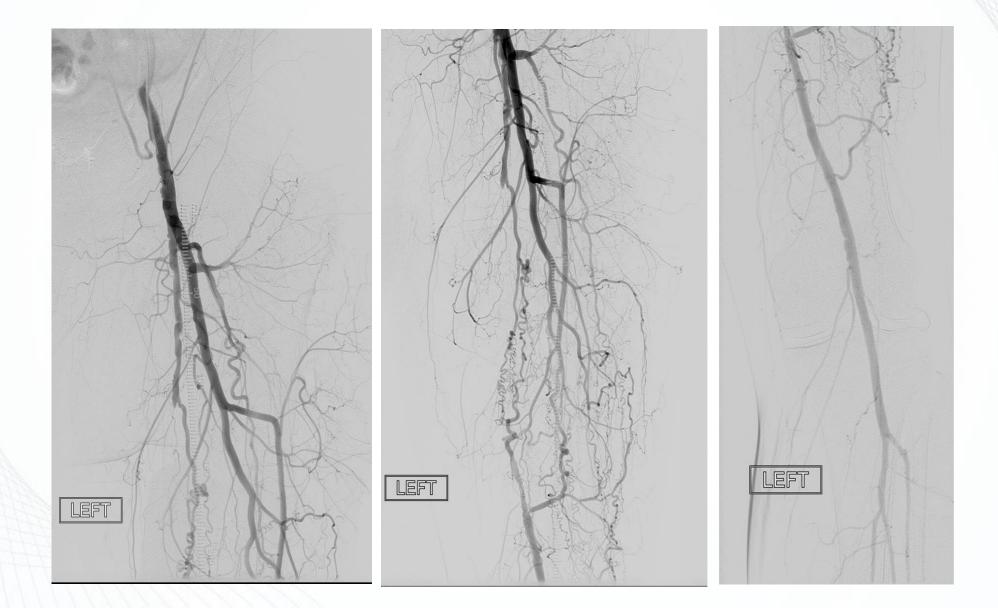
IN.PACT SFA Trial Primary patency¹ through 3 years



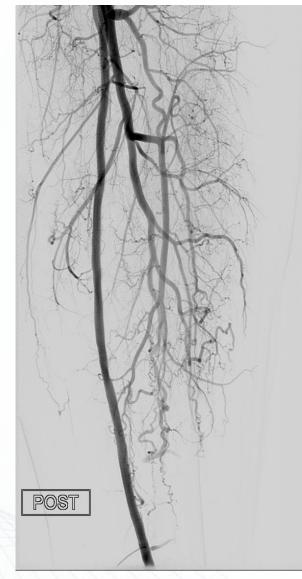
 Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 36 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment).

2. Number at risk represents the number of evaluable subjects at the beginning of each 30-day window.

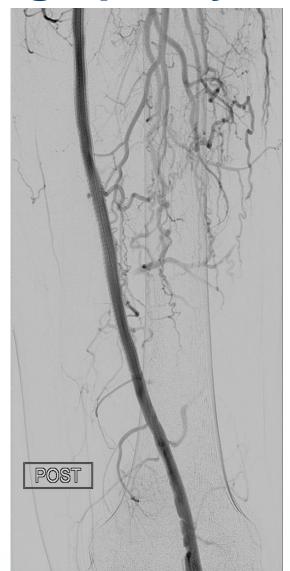
Long SFA Occlusion

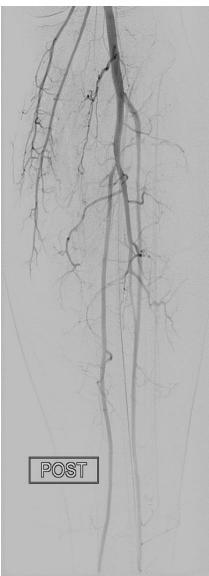


Following Drug coated balloon angioplasty



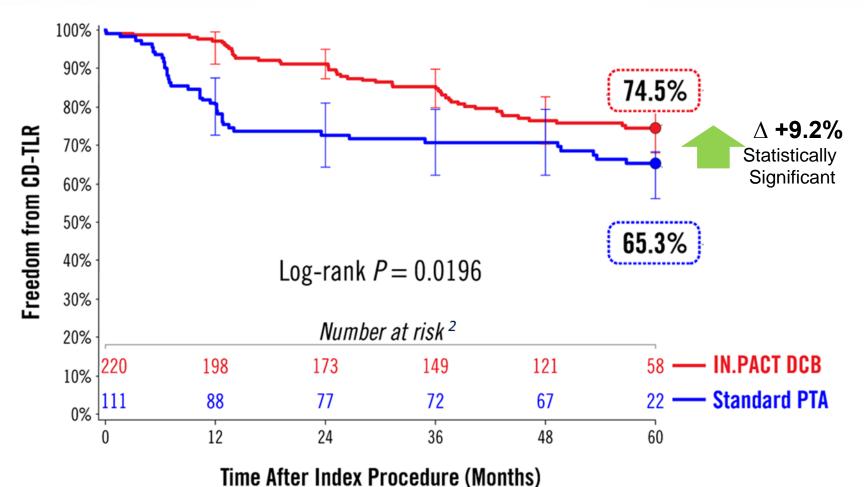
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CVRF

IN.PACT SFA Trial Freedom from CD-TLR¹ through 5 Years



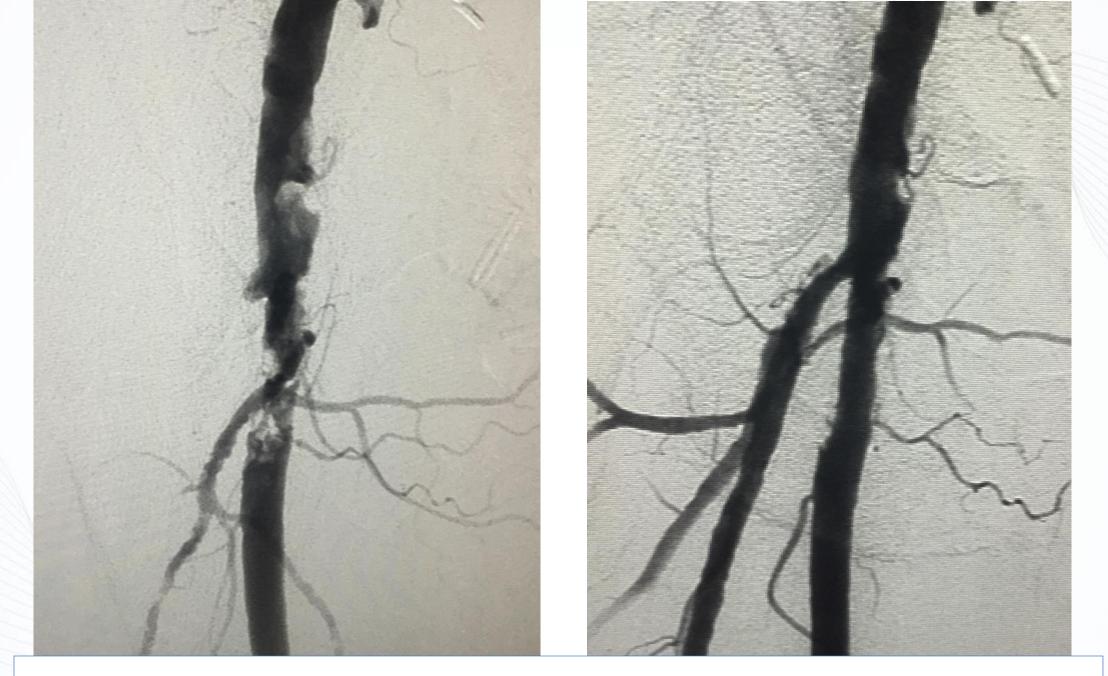
1. Clinically-driven TLR adjudicated by an independent Clinical Events Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI.

2. Number at risk represents the number of evaluable subjects at the end of each 30-day window for months 12, 24, and 36, and the end of each 60-day window for months 48 and 60.

Better devices for Calcium







Calcified Common Femoral and SFA Disease – Atherectomy + DCB

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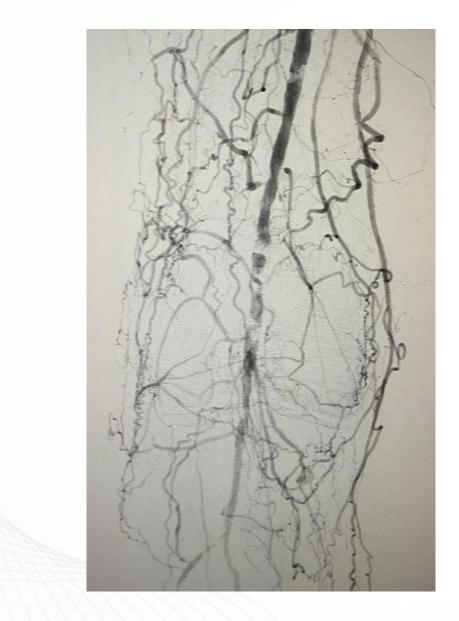
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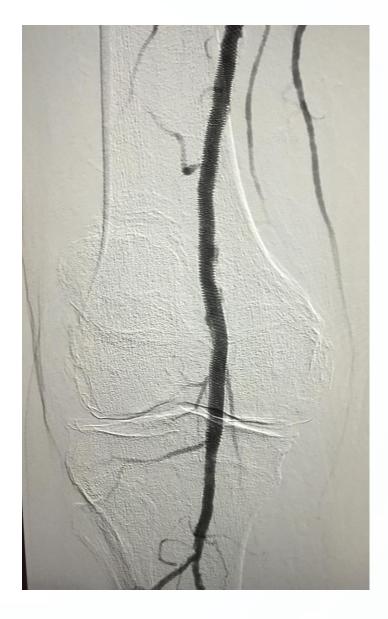
Woven Nitinol Design



CVR

Popliteal Artery Stenting

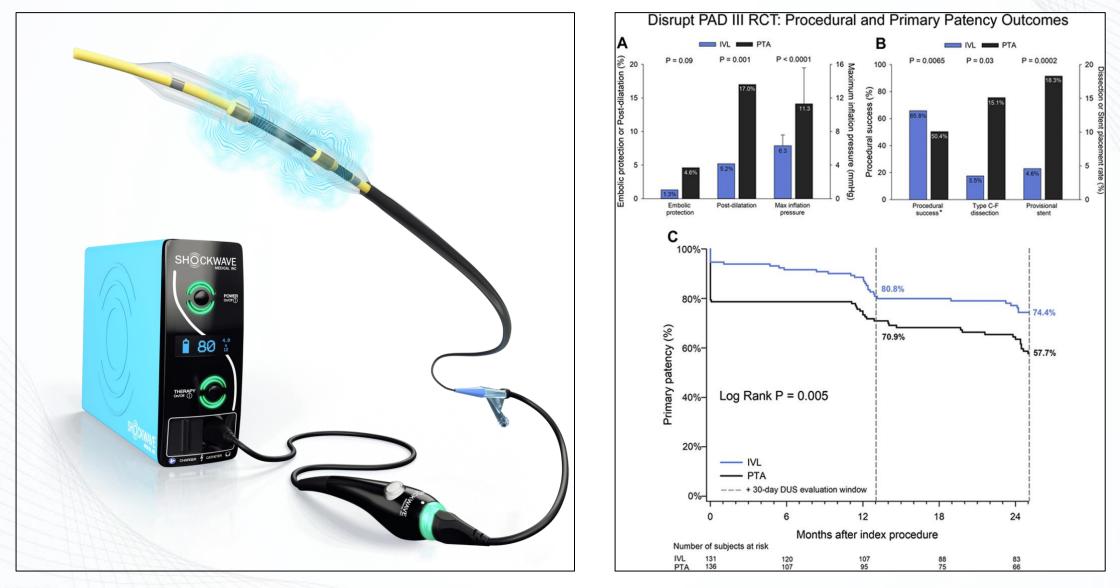






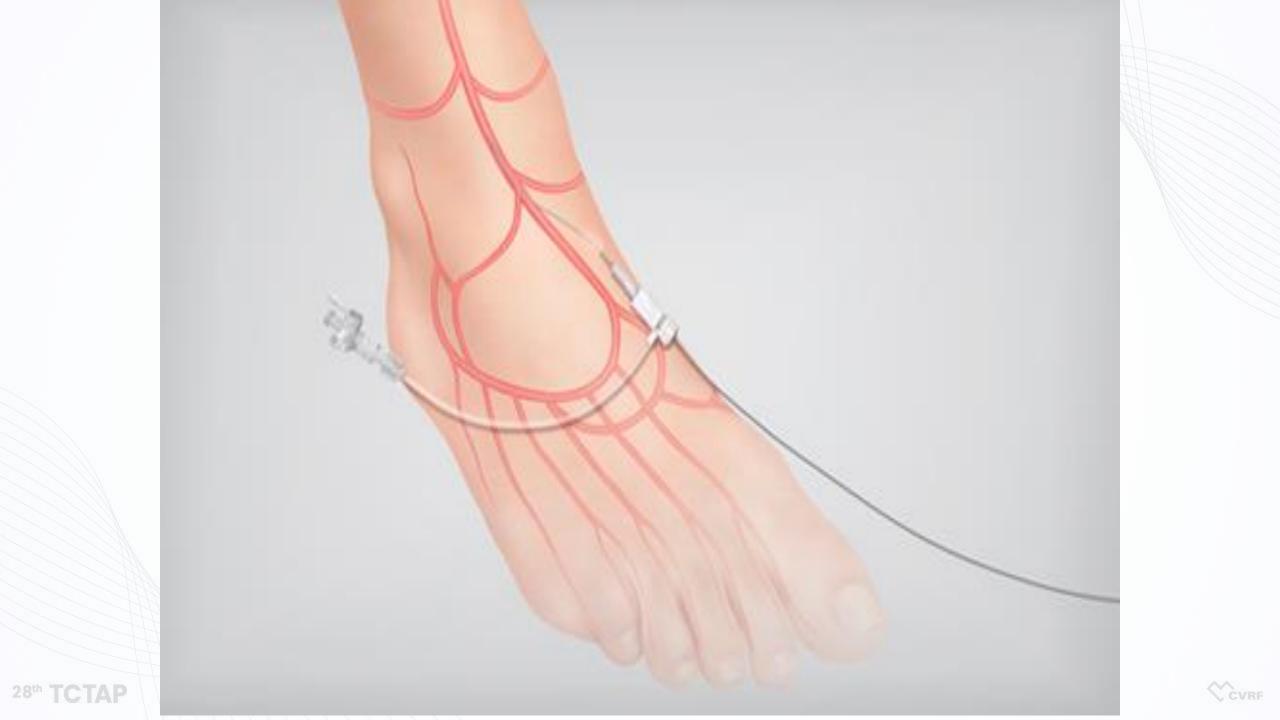


Shockwave (IVL)



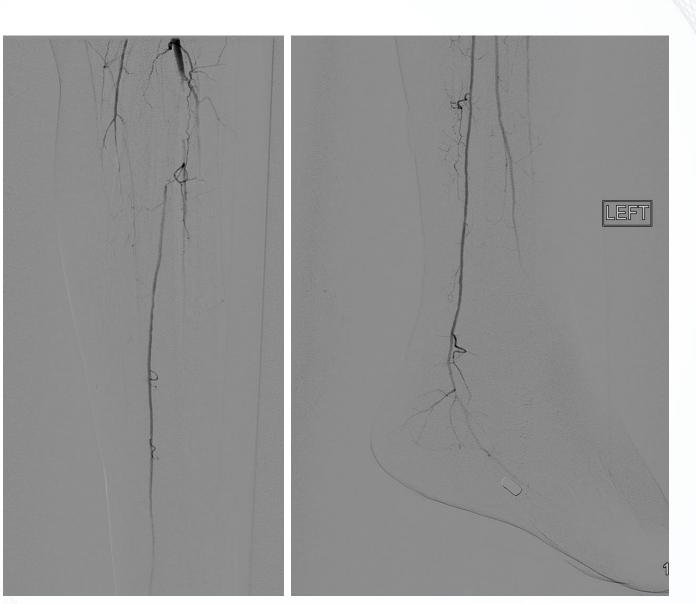
Advanced Techniques for Limb Salvage

- Distal and multivessel intervention
- Pedal and tibial access
- Advanced CTO techniques
- Recanalization through collaterals
- Plantar arch recanalization
- Transcatheter arterialization of the deep veins



Retrograde Access

- 61 yo AAF with DM, CAD s/p CABG, and ESRD on dialysis
- CLI with rest pain and ischemic ulcers of medial distal lower leg
- Subtotal popliteal occlusion and infrapopliteal disease
- No usable vein



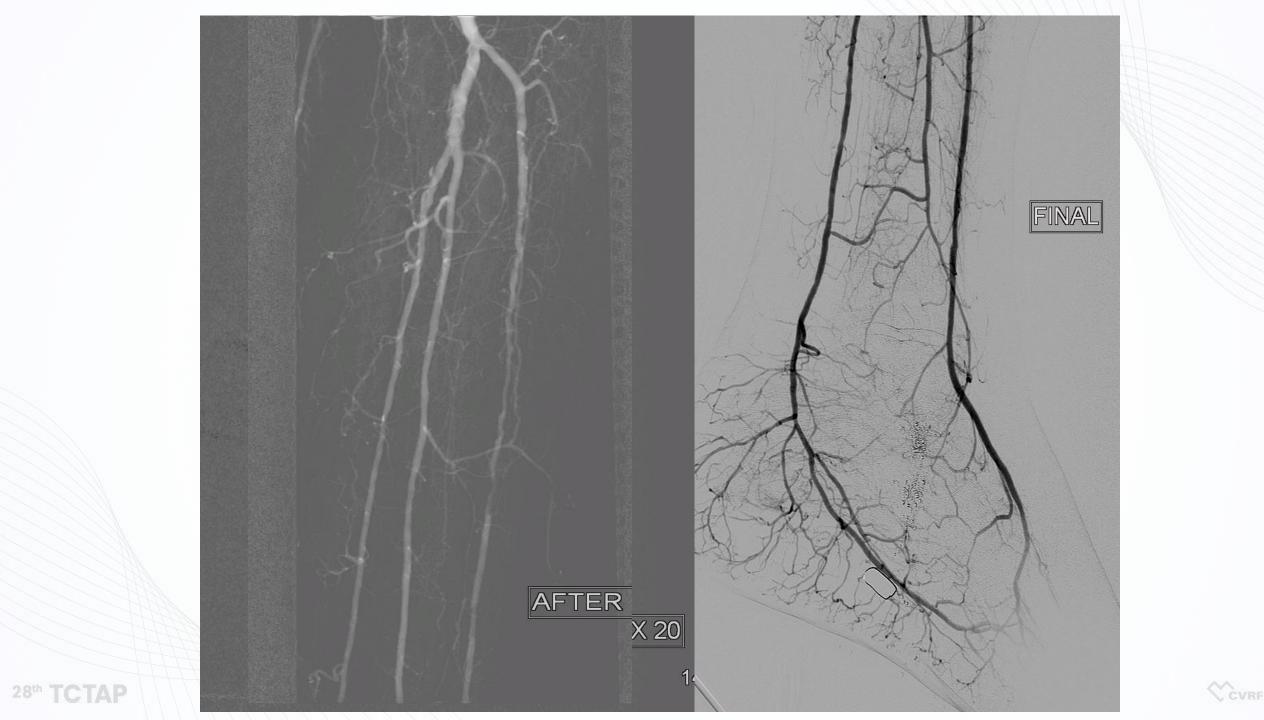


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Case history

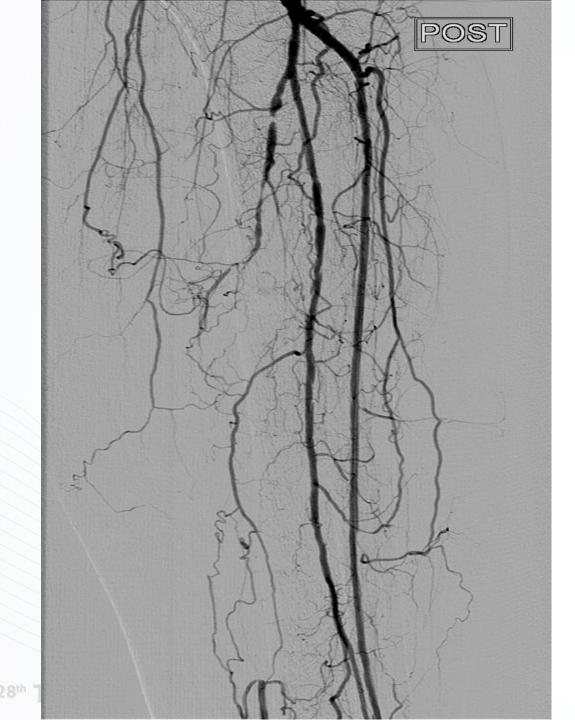
- 67 year old male
- Long standing diabetes mellitus
- Peripheral artery disease
- Large non-healing ulcer on plantar aspect of foot unable to walk
- Failed attempt at revascularization at another hospital. Told he would likely need below knee amputation
- He came to me for a second opinion



Baseline Angiography









Wound healing





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坝占 由了 酒 2014.11.04.17 杨素 Dr. John Laind UC Davis Medical Center 4860 Y Street Systemszo Sacnamento, CR USA 9 邮政编码 28th TCTAP

Dear Dr. Laird,

Gasping for thin air and standing wobbly on the two legs that you and your good work preserved for me, I stood at the base of Mt. Everest today - a thing I had hoped to live to see since childhood!

I couldn't let the day end without thanking you for your skills and care that led me here. You know, when first confronted with the very real and probable possibility of loosing my leg, my true horror was not over becoming an amputee, but in the end to travel as I have experienced it.